

"GREATER ACCESS TO AFFORDABLE PHARMACEUTICALS ACT"

| CURRENT HATCH-WAXMAN | FDA PROPOSED RULE | S. 812 AS PASSED BY SENATE | GREGG-SCHUMER-McCAIN-KENNEDY |
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| FILING PATENT INFORMATION WITH FDA | | | |
| <p>Current law requires brand companies to file patent information, which FDA lists in the Orange Book. These patents can determine whether the effective approval of a generic drug is delayed until the patent has expired or has been successfully challenged.</p> <p>No opportunity for a generic company to challenge an incorrect listing and ask that information in the Orange Book be corrected or a patent be de-listed. This is significant since the listing can trigger a 30-month stay. Further, the FDA does not currently review patent information before listing in the Orange Book and has never brought an enforcement action against a brand company for incorrectly listed patents.</p> | <p>Requires clarification of information included in patent listings, similar to S.812.</p> <p>No new penalty for failure to list relevant patents or failure to provide complete information.</p> <p>No new enforcement mechanism. FDA does not intend to change its current ministerial role in listing patent information without review.</p> | <p>Further clarifies the patent information required (e.g., requires identification of the approved indication a method of use patent claims, and clarification of the types of claims in a patent). Requires declaration that information is complete and accurate.</p> <p>Stipulates that failure to file patent or information about a patent that protects a brand drug means that the brand company is not able to assert the patent against an ANDA applicant.</p> <p>Includes new enforcement mechanism: provides a cause of action for generic company to challenge an inappropriately listed patent and request court to order that a brand company correct patent information or delist a patent. This cause of action only applies to patents listed with the FDA within 30 days after the New Drug Application (NDA, i.e., brand drug) application is approved (the same patents for which a 30 month stay is available). Bill clarifies that no monetary damages may be awarded as a result of this cause of action – the only remedy that can be sought is the de-listing from or correction of patent information in the Orange Book.</p> | <p>No provision.</p> <p>In patent infringement case, court may consider failure to file patent information as basis for not awarding treble damages.</p> <p>Includes new enforcement mechanism: provides for a counter-claim in patent infringement litigation by which generic applicant may seek to correct or delete patent information. The bill clarifies that no monetary damages may be awarded as a result of this counterclaim – the only remedy that can be sought is the de-listing from or correction of patent information in the Orange Book – and that the counterclaim does not authorize a claim in any other proceeding.</p> |

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| 30 MONTH STAY | | | |
| <p>Multiple 30-Month Stays Permitted</p> <p>When filing an Abbreviated New Drug Application (ANDA, i.e., generic drug application) with the FDA, the generic applicant must certify that its generic will not infringe on the patent rights of the brand-name company. To comply with this requirement, the generic applicant may certify that:</p> <ul style="list-style-type: none"> I) the drug has not been patented; II) the patent has already expired; III) the patent is about to expire and the generic will not enter the market until it does; or IV) the patent is invalid or will not be infringed by the generic. <p>If the generic company claims the fourth option (called a "Paragraph IV" certification), it must give immediate notice to the patent holder of its intent to market the drug. The brand company then has 45 days to file suit if it believes the generic will infringe the patent. If a brand company sues, the FDA must automatically stay (i.e., delay) generic approval for 30 months, or until resolution of the litigation, whichever occurs first.</p> <p>If the brand company lists a new patent on the drug after the ANDA's application has been filed, the ANDA must submit an additional certification to FDA with regard to that patent. If the brand company sues, an additional 30-month</p> | <p>One 30-Month Stay, no time restriction</p> <p>Allows for single 30-month stay, but does not put a time restriction on when this stay can be triggered. If no patent is challenged in original ANDA application, 30-month stay is triggered if and when subsequently listed patent is challenged by ANDA applicant. By contrast, under both S. 812 and the Gregg-Schumer-McCain proposal, a 30-month stay is triggered (if triggered at all) at the time the ANDA application is filed and runs concurrent with ANDA approval, as was the original intent in Hatch-Waxman. Because the proposed rule allows the stay to be triggered after ANDA is filed (up to the day before ANDA approval), the proposed rule maintains the potential for last-minute delays.</p> <p>Provides no mechanism for certain resolution of patent disputes prior to ANDA marketing. Failure to provide a time frame during which brand company must bring suits of patent infringement provides incentive for brand company to wait to sue until after ANDA is on the market, when it will be able to collect treble damages. In the face of this uncertainty, generic drug company may choose not to enter the market at all.</p> | <p>One 30-Month Stay, limited to patents filed within 30 days following NDA approval</p> <p>One automatic 30-month stay is available only on Paragraph IV challenges to patents that were listed in FDA's Orange Book within 30 days following NDA approval.</p> <p>Other drug patents listed after NDA approval would be subject to preliminary injunction standard.</p> <p>Requires patent holder to bring action for patent infringement within 45 days of notice of ANDA patent challenge (as they must under current statute to get the automatic stay currently available). If patent owner does not bring a patent infringement action within 45 days, generic approval can be effective on day 45, and the patent owner may not subsequently bring an infringement action for that patent against the generic drug made by that applicant, or against any sellers or distributors of that applicant's version of the generic drug.</p> <p>(This statute of limitations is a key counterbalance to the elimination of multiple 30-month stays, as the elimination of the automatic stays also removes a brand's incentive to bring its suit prior to ANDA marketing. If the ANDA is unable to resolve patent infringement questions</p> | <p>One 30-Month Stay, limited to patents filed at least 1 day before ANDA is filed</p> <p>One automatic 30-month stay is available only on Paragraph IV challenges to patents that were published in FDA's Orange Book at least 1 day before ANDA filing.</p> <p>Certifications to patents that were published in FDA's Orange Book at least 1 day before ANDA filing that are changed to a Paragraph IV certification after ANDA filing also trigger a 30-months stay.</p> <p>For a patent published in FDA's Orange Book after ANDA filing, generic applicant must certify to it but no additional 30-month stay will be issued. Patent owner may sue for patent infringement, but if it does not do so within 45 days of receiving notice of the Paragraph IV certification, ANDA applicant may seek a declaratory judgment that the patent is invalid or not infringed.</p> <p>(This right to a declaratory judgment is the counterbalance to the elimination of multiple 30-month stays, as it allows the ANDA applicant to seek resolution of patent infringement questions before marketing its drug.)</p> |

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| stay is granted. In this way, the filing of new patents can cause "stacked", or successive, 30-month stays. | | prior to marketing its drug, it risks being sued by patent owner after it enters the market, thereby risking having to pay treble damages (triple the brand's lost profits).) | |
| 180-DAY GENERIC EXCLUSIVITY | | | |
| <p>Current law provides an incentive to challenge potentially invalid patents; if a generic is the first challenge a patent, it gets 180 days of generic exclusivity (i.e., protection from competition from other generic companies).</p> <p>The exclusive right to market the drug is retained by the first generic applicant and no other applicant can market until that 180-day period is triggered and runs its course.</p> <p>The 180-day clock is triggered by either:</p> <ol style="list-style-type: none"> 1) a district court decision, or 2) the first commercial marketing of the generic. <p>If the generic is concerned about an appeal of the district court decision, and does not wish to market its drug while litigation is pending (and risk treble damages), its exclusivity period will be lost while the litigation proceeds.</p> <p>If the generic applicant that holds the exclusivity settles or colludes with a brand company and agrees not to go to market, the 180-days is never triggered and all other generics are precluded from coming to market.</p> <p>The exclusivity incentive is thus lost and does not pass to the next generic.</p> | No provision. | <p>Modified "Use-or-Lose" Exclusivity</p> <p>ANDA applicant forfeits its right to 180-day exclusivity for any of the reasons articulated below. If an ANDA applicant forfeits exclusivity, it can be available to a second generic company, but only if no other generic competitors are ready to come to market.</p> <p>The 180-day clock is triggered by either:</p> <ol style="list-style-type: none"> 1) an appellate court decision; or 2) the first commercial marketing of the generic. <p>Applicant forfeits exclusivity if it:</p> <ul style="list-style-type: none"> • Reaches a financial settlement with the brand name to stay out of the market until the patent(s) have expired; • Fails to go to market within 60 days of ANDA approval; • Fails to get FDA approval within 30 months; • Fails to challenge a new patent within 60 days; • Withdraws its application; • Is determined by the Federal Trade Commission to have engaged in anti-competitive | <p>"Use-or-Lose" Exclusivity</p> <p>ANDA applicant forfeits its right to 180-day exclusivity for any of the reasons articulated below. If an ANDA applicant forfeits exclusivity, it is not available to any other generic company, and generic approvals are immediately effective.</p> <p>The 180-day clock is triggered by either:</p> <ol style="list-style-type: none"> 1) an appellate court decision; or 2) the first commercial marketing of the generic. <p>Applicant forfeits exclusivity if it:</p> <ul style="list-style-type: none"> • Reaches a financial settlement with the brand name to stay out of the market until the patent(s) have expired; • Fails to go to market within 60 days of ANDA approval; • Fails to get FDA approval within 30 months; • Fails to challenge a new patent within 60 days; • Withdraws its application; • Is determined by the Federal Trade Commission to have engaged in anti-competitive activities. |

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| | | <p>activities.</p> <ul style="list-style-type: none"> Also, bill clarifies that ANDA will not forfeit exclusivity until final decision of appellate court. | <ul style="list-style-type: none"> Also, bill clarifies that ANDA will not forfeit exclusivity until final decision of appellate court. |
| FAIR TREATMENT OF INNOVATORS | | | |
| Requires generic to provide notice to brand company of claims of invalidity or non-infringement | No provision. | <p>ANDA applicant must provide NDA holder with additional, detailed legal basis of assertion that patent is invalid or not infringed.</p> <p>Clarifies that a preliminary injunction in a drug patent infringement case may be granted notwithstanding the availability of monetary damages from the generic.</p> | <p>No provision.</p> <p>No provision (because there is no preliminary injunction standard in the bill).</p> |
| BIOEQUIVALENCE | | | |
| Under current law, bioequivalence is demonstrated through blood level studies. In some circumstances, FDA has permitted limited human data to be submitted in support of products for which blood level studies can not be done (such as topicals and inhalants). | No provision. | <p>Clarifies that FDA's existing regulations have the effect of law.</p> <p>Clarifies that FDA may amend them if necessary.</p> <p>Clarifies that FDA's authority over biological products under the Federal Food, Drug, and Cosmetic Act is not changed.</p> | <p>Allows FDA to establish bioavailability and bioequivalence of drug products that are not intended to be absorbed systematically using alternative scientifically valid methods provided they do not yield significant differences in therapeutic effect and safety.</p> <p>Clarifies that FDA's authority over biological products under the Federal Food, Drug, and Cosmetic Act is not changed.</p> |